

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9094

Bartle, J.

June 21, 2013

Myra J. Hilton ("Ms. Hilton" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Johnny B. Hilton, Ms. Hilton's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert N. Notske, M.D., F.A.C.C., F.A.C.P. Dr. Notske is no stranger to this litigation. According to the Trust, he has signed at least 45 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated June 17, 2002, Dr. Notske attested in Part II of Ms. Hilton's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to

3. (...continued)
 contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$501,985.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Guy E. Katz, M.D., F.A.C.C., stated that claimant had moderate mitral regurgitation, which he measured at 41%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In June, 2005, the Trust forwarded the claim for review by Henryk Kafka, M.D., F.R.C.P.C., F.A.C.P., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Kafka concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant had moderate mitral regurgitation because the echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Kafka stated:

4. Dr. Notske also attested that Ms. Hilton suffered from mild aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

This tape is simply a series of loops placed onto tape. It is difficult to get a feel for wht [sic] is happening since we never see more than 1 or 2 beats at a time. The impression is that of trivial or mild [mitral regurgitation]. ON [sic] stop frame analysis, I never see the systolic jet last more than 3 frames.⁶

Based on Dr. Kafka's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Hilton's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted declarations from Dr. Notske and Dr. Katz. Claimant also submitted the report of a subsequent echocardiogram performed on May 24, 2004, which, according to claimant, demonstrated progression in the level of her mitral insufficiency. In his declaration, Dr. Notske stated that:

This Echocardiogram was performed by a Laboratory contracted and approved by "the Trust". To best exemplify the findings, they simplified the larger study by presenting the pertinent findings in well presented "loops". The Mitral Regurgitation lasts sufficiently to make the diagnosis according to

6. In a certification submitted in November, 2005, Dr. Kafka expounded on this statement, noting that "[o]n stop frame analysis, I never see the systolic jet last more than 3 frames, that is, the duration of the jet is <100 msec."

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Hilton's claim.

Feigenbaum. Also, in both Weyman and Feigenbaum there is no specific limitation to the number of beats, just that sufficient views be able to be seen and that the largest area should be used regardless of the plane in which it is recorded. This Echocardiogram does not leave one with the "impression ... of trivial or mild [mitral regurgitation]". On the contrary, it demonstrates at least moderate Mitral Regurgitation.

Dr. Katz also confirmed his original findings after reviewing claimant's June 17, 2002 echocardiogram for a second time. Specifically, Dr. Katz stated, "I still find moderate mitral regurgitation based on an RJA/LAA greater than 20% of the left atrial area, as required for Matrix Level II benefits under that [sic] AHP Settlement Agreement." Dr. Katz also noted that Ms. Hilton was his patient and that he reviewed subsequent echocardiograms performed on January 3, 2003 and May 24, 2004. Regarding these subsequent echocardiograms, Dr. Katz stated, "Both echocardiograms continue to demonstrate moderate mitral regurgitation at 27% and 30% RJA/LAA, respectively, further supporting my interpretation of Ms. Hilton's moderate mitral diagnosis in her June 17, 2002 echocardiogram."⁸

The Trust then issued a final post-audit determination, again denying Ms. Hilton's claim. Claimant disputed this final determination and requested that the claim proceed to the show

8. Claimant submitted a report for her May 24, 2004 echocardiogram, but did not submit a report for her January 3, 2003 echocardiogram. Claimant did not submit copies of the tapes for either of these echocardiograms. In any event, these echocardiograms do not provide a reasonable medical basis for Dr. Notske's representation that claimant had moderate mitral regurgitation based on her June 17, 2002 echocardiogram.

cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Hilton's claim should be paid. On December 9, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5887 (Dec. 9, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 8, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Hilton argues that her attesting physician's Green Form response is supported by a reasonable medical basis because both Dr. Notske and Dr. Katz agreed that claimant's RJA/LAA ratio was greater than 20% and they followed the Feigenbaum and Weyman texts. Claimant also contends that the auditing cardiologist simply criticizes the quality of the echocardiogram, which was performed as part of the Trust's Screening Program,¹⁰ rather than providing any basis to undermine the reasonableness of the attesting physician's finding of moderate mitral regurgitation. In addition, claimant asserts that, "[u]nlike the Trust Screening cardiologist, the auditing cardiologist [failed] to provide any actual measurements to

10. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

support his interpretation of the severity of the mitral valve regurgitation" and did not reference the Feigenbaum and Weyman texts to support his conclusion. Finally, claimant argues that the Trust's only other argument, regarding backflow, is a "red herring" that "proves itself wrong based on the demonstrated velocity of the regurgitant jet, bad math by the Trust and the fact that the auditor did not claim that it was backflow."

In response, the Trust argues that claimant has failed to meet her burden of establishing a reasonable medical basis for her claim because Dr. Notske and Dr. Katz did not and could not identify a "sustained, substantial jet" or "any appreciable jet" of mitral regurgitation because the supposed mitral regurgitant jet upon which Dr. Notske and Dr. Katz relied only lasted 3 frames. According to the Trust, a true jet of mitral regurgitation must last at least one-tenth of a second, or at least 4 successive frames based upon a frame rate of 30 frames per second. The Trust also notes that the only frame identified on the echocardiogram "occurred in early systole, just as the mitral valve closes on the QRS," which it argues supports its contention that the jet upon which Dr. Notske and Dr. Katz relied is non-regurgitant flow or backflow. The Trust further contends that Dr. Katz's participation in the Screening Program did not "transform[] him into an agent of the Trust or conclusively validate[] other echocardiograms he may have performed in his independent professional capacity." Finally, the Trust contends that: (1) Dr. Kafka was not required to provide exact

measurements of the regurgitant jet; and (2) neither the Settlement Agreement nor the Audit Rules required the auditing cardiologist to support his finding of mild mitral regurgitation by citing to the Feigenbaum and Weyman texts.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson found:

In reviewing the transthoracic echocardiogram of 6/17/02, my visual estimate is that there is only mild mitral regurgitation with normal mitral leaflet morphology. In the parasternal long axis there are two different cardiac cycles which demonstrate only mild [mitral regurgitation]. In the apical views there is only one cardiac cycle demonstrating color flow imaging in each of the 3 standard views (4-chamber, 2-chamber, long axis). Each view reveals only mild mitral regurgitation. The mitral regurgitation jet is of short duration, occupying less than half of systole (which confirms that it is only mild).

There was no mitral regurgitation tracing on the tape for me to critique. The mitral regurgitation jet is a small central jet.

In summary, it would be impossible for a reasonable echocardiographer to interpret the severity of this mitral regurgitation as moderate. There is no reasonable medical basis for the Attesting Physician's claim that this [claimant] has moderate mitral regurgitation, even taking into account inter-reader variability. Myra J. Hilton has only mild mitral regurgitation.

In response to the Technical Advisor Report, claimant argues that Dr. Abramson failed to identify any violations by Dr. Notske and Dr. Katz of specific provisions of the Settlement Agreement or medical literature. Claimant further asserts that "regurgitant flow" does not need to last a certain duration and there is "no specific limitation to the number of beats, just that the sufficient views be able to be seen" Finally, claimant assumes that the Technical Advisor did not use the most common approach to quantify Ms. Hilton's level of mitral regurgitation, which would require measurement of the "maximum turbulent flow area," including the "surrounding flow area." According to claimant, this explains the difference in the findings by the Technical Advisor and claimant's physicians.¹¹

After reviewing the entire show cause record, we find claimant's arguments are without merit. We disagree with claimant that the declarations of her physicians establish a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can

11. Claimant also contends Dr. Abramson did not disclose what protocol she used in reaching her determination. To the contrary, Dr. Abramson stated in her report, "My review of this Claimant's Record was performed in accordance with the standards set forth in the Green Form and in the Nationwide Class Action Settlement Agreement with American Home Products Corporation."

include, among other things, failing to review multiple loops and still frames, failing to examine the regurgitant jet throughout a portion of systole, and characterizing low velocity flow as mitral regurgitation. Mem. in Supp. of PTO No. 2640 at 11-13, 15, 22, 26. We have further found that "[o]n a color flow Doppler echocardiogram, mitral regurgitation will thus display as a high velocity, mosaic blue/green teardrop shaped jet that borders the mitral valve leaflets and expands into the left atrium throughout at least a portion of systole." Id. at 10-11 (footnote omitted).

Here, Dr. Kafka explained that he did not observe "more than 1 or 2 beats at a time" or any systolic jet lasting more than three frames. Dr. Abramson determined that claimant's mitral regurgitant jet was "of short duration, occupying less than half of systole," which confirmed that claimant had only mild mitral regurgitation. Claimant does not dispute that Dr. Kafka observed only three frames of a systolic jet and, in fact, concedes that the fourth, fifth, and sixth frames were not included on the loops presented on the echocardiogram tape. Claimant also does not dispute Dr. Abramson's finding that the regurgitant jet had a short duration that occupied less than half of systole. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation.

Although claimant argues that the echocardiogram tape consists of "representative loops and frames," claimant fails to

rebut adequately the Trust's argument that the jets visible on the tape are not representative of mitral regurgitation. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of regurgitation are representative of the level of regurgitation throughout an echocardiogram."¹² Memo. in Supp. of PTO No. 8659 at 10 (Aug. 8, 2011) (quoting Memo. in Supp. of PTO No. 6997 at 11 (Feb. 26, 2007)); see also In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). As we have stated previously, "'To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.'" Memo. in Supp. of PTO No. 8659 at 10.

Ms. Hilton has failed to demonstrate that the loops presented on her echocardiogram tape are representative of moderate mitral regurgitation that can be observed throughout her echocardiogram. Instead, she relies on her interpretation of the Feigenbaum and Weyman texts that there is no specific limitation on the number of beats required to evaluate a claimant's level of regurgitation and that regurgitant flow does not need to last a

12. As stated above, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

certain duration of systole. These contentions are inconsistent with the Settlement Agreement and our prior interpretation of the Settlement Agreement.¹³

We also reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of the claim was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

13. It also appears that claimant's physicians included "non-high velocity flow" or "lower flow spray" in reaching their conclusion that claimant's echocardiogram demonstrated moderate mitral regurgitation. We repeatedly have held that the inclusion of "lower flow spray," or low velocity flow, constitutes conduct beyond the bounds of medical reason for purposes of the Settlement Agreement. See, e.g., Mem. in Supp. of PTO No. 8598 at 8-11 (Feb. 8, 2011).

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

In addition, we disagree with claimant's argument that the auditing cardiologist and Technical Advisor inappropriately relied on visual estimation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not require that actual measurements be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See Mem. in Supp. of PTO No. 2640 at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be

made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and claimant's argument is contrary to the "eyeballing" standards we previously evaluated and accepted in PTO No. 2640.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Hilton's claim for Matrix Benefits and the related derivative claim submitted by her spouse.